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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,286	12/07/1999	MICHAEL GROLL	P564-9039	3782
6449	7590	01/21/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			CLOW, LORI A	
1425 K STREET, N.W.			ART UNIT	
SUITE 800			PAPER NUMBER	
WASHINGTON, DC 20005			1631	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/381,286

**Applicant(s)**

GROLL ET AL.

**Examiner**

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28,30 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 30, and 32-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' response, filed 27 October 2004, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 28, 30, and 32-36 are currently pending.

#### **Claim Rejections - 35 USC § 112-1<sup>st</sup> Paragraph-1<sup>st</sup> Paragraph**

##### *Enablement*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 30, and 32-36 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the previous Office Action.

Applicant argues that "the novel purification process of the present invention results in proteasomes sufficiently pure to obtain crystals, and from these crystals, routine procedures known in the art and described in the specification can readily be used by one of ordinary skill in the art to identify inhibitors to the proteasomes". This is not persuasive in that the general purification steps recited in the claims involving multiple column steps of random cellular

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extracts, which are not necessarily proteasomes, would not result in a pure crystal such that one of skill in the art would be able to model the crystal. It is unclear what portion or portions, recited in the claims, are those argued by Applicant to be the “novel” method of purification/crystallization.

Applicant argues that “the acknowledgement by the Examiner that the specification indeed provides a description of how one can analyze the crystal structures to identify inhibitors using-computer aided modeling is itself evidence of enablement”. This is not persuasive. The Examiner acknowledges that one can analyze, using computer modeling of a purified crystal, the specific proteins isolated from yeast and crystallized in the presence of an inhibitor, as demonstrated in the specification. However, these limitations are not in the claims and therefore the claims are not enabled.

Applicant further argues that “the Examiner is incorrect in requiring the modeling steps be specifically recited in the claims”. This is not persuasive because the Examiner has not required that modeling steps be in the claims. Rather, the Examiner has stated that without such steps one would not know how to analyze or process crystal data. The Examiner has simply pointed to specific embodiments that **are** enabled by the specification. These are not in the claims. Absent a sufficient quality crystal to enable modeling, the new limitations do not provide enablement to the claims.

Applicant argues several points in reference to Furet et al. (J. Med. Chem. (2004) Vol. 47, pages 4810-4813) for support of enablement of the instant claims. However, these arguments are moot in view of the fact that post-filing art cannot provide enablement. Applicant is reminded the claims must be fully enabled at the time of filing.

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The Furet et al. paper and the instant specification refer **only** to yeast proteasome crystallization. The paper and the specification refer to nothing other than yeast proteasomes crystallized, under specific conditions, in the presence of an inhibitor.

It is noted that computer programs for modeling **once a crystal of sufficient quality** has been obtained are well known in the art. However, the crystal of sufficient quality is imperative in this process. For the reasons previously set forth and set forth above, the rejection is maintained.

#### *Written Description*

Claim 36 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons set forth in the previous Office Action. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that “the specification clearly describes how to obtain inhibitors using the present method and what characteristics define such inhibitors”. This is not persuasive in that the specification fails to define an inhibitor such that one of skill in the art would know the structure, sequence etc... associated with that inhibitor. Applicant is reminded that written description must be supplied by the specification at the time of invention. Applicant cannot rely on prior art or post-published to supply written description for the claimed invention.

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**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 30, and 32-3636 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the previous Office Action.

Applicant argues that “analyzing the structure...is clear, particularly in light of the description on how to design inhibitors based on structure of the crystals”. This is not persuasive because the metes and bounds of “analyzing” are still unclear. Just because one can supposedly design inhibitors, does not mean that the steps of the analysis are clear. What steps does “analyzing” encompass, for example? Clarification is requested.

Applicant further argues that “claim 32 is clear as written given the description in the specification”. Applicant is relying on an argument directed to enablement, which has been addressed above. The specification fails to define **what** modification is intended. Which amino acid sequences, for instance, are modified? Which portion of the crystal data is modified? Clarification is requested.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

January 14, 2005  
Lori A. Clow, Ph.D.  
Art Unit 1631

*Lori A. Clow*

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*  
1/18/05